

Optimal EVAR Fixation:

Suprarenal Fixation Is Safe, Effective, and Necessary

BY ROY K. GREENBERG, MD

Recent large, prospective, randomized trials have provided evidence justifying the treatment of aneurysms >5.5 cm in patients fit for open repair.^{1,2} Although questions remain with respect to the long-term durability of endovascular aneurysm repair and its application to higher-risk patient populations,^{3,4} it is blatantly clear that the opinion expressed by Collin and Murie in the *British Journal of Surgery* in 2001,⁵ "Endovascular treatment of abdominal aortic aneurysms: a failed experiment," was incorrect.

Despite widely spread enthusiasm for less-invasive repairs, endoprotheses represent a disruptive technology, and therefore must be subject to continuous scrutiny and criticism to encourage the evolution required to improve the devices, the technical aspects of the procedure, and physician judgment. Today, we are in an enviable situation: we have learned that endovascular aneurysm repair is a reasonably good choice for most patients with acceptable anatomy; however, do we know which device to use? Are all implants equal? Will the

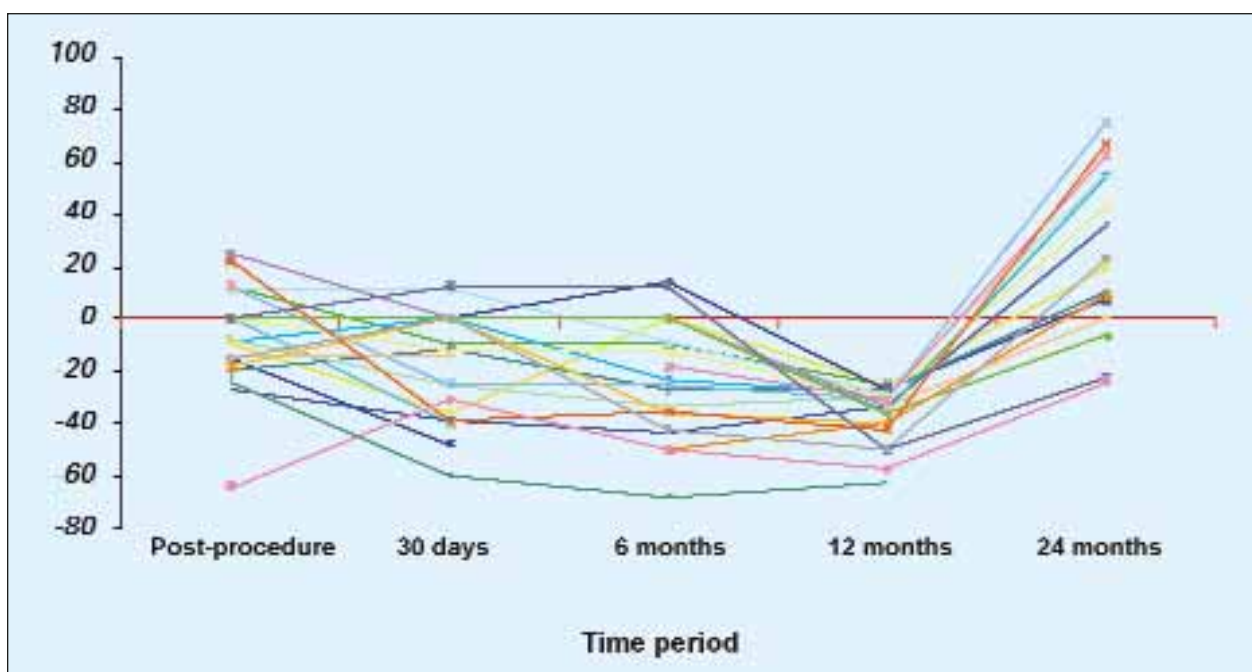


Figure 1. This graph depicts the change in creatinine clearance for each patient that developed a creatinine rise >30% (Two patients, one from the endovascular group and one from the open surgical group, who required hemodialysis were excluded from this analysis). It is the universal improvement in creatinine clearance between 12 and 24 months that reassures us that suprarenal stenting is very unlikely to be associated with adverse renal function. The more likely culprits are atheroemboli and repeated contrast administration.

results of a specific physician with a given prosthesis imply the ability to obtain equivalent results by other physicians? Ultimately, there exists too much art rather than science in device selection, implantation techniques, and follow-up paradigms. We do our patients a disservice by not carefully reviewing the data at hand, and applying this information to everyday practice. The specific question entertained by myself and my opponent is whether endografts should utilize the suprarenal aorta for fixation purposes with an uncovered suprarenal stent. The issue can be reduced to two fundamental questions: is suprarenal stenting necessary (implying there is likely a problem with infrarenal fixation systems), and, if so, is it harmful (to the renal arteries)?

"It is entirely possible that migration will be the ultimate failure mode for most endovascular repairs—if these devices are placed into patients who live long enough."

THE NECESSITY OF SUPRARENAL STENTING

Migration is a problem. It is a major issue in long-term follow-up studies and has been noted to occur with nearly all endoprostheses. It is entirely possible that migration will be the ultimate failure mode for most endovascular repairs—if these devices are placed into patients who live long enough (ie, patients fit for open surgical repair). I feel the need to reiterate history to avoid reliving it. The first report on device migration was published by the Malmö group in 1997,⁶ subsequent studies noted early grafts to have a migration incidence of >40% using an infrarenal device.⁷ In many cases, the device was placed a significant distance below the renal arteries. These studies concluded that devices should utilize active fixation systems and be placed in close proximity to the renal arteries.

The Malmö analyses prompted the development of devices utilizing active fixation (hooks and barbs) as well as stenting into suprarenal aorta, which was first reported in 1997.⁸ Analyses of other devices (with only infrarenal fixation), subsequent to the Malmö paper and as late as 2003, touted very high device migration rates, approaching or even exceeding 40% in the setting of only intermediate term follow-up.⁹⁻¹¹ Some of the devices used in the aforementioned reports are still being implanted today. Why are these migrations occurring? Is it the physicians, the devices, or the patients who were selected for treatment that are causing this problem? The answer to all of these questions is yes.

Have we grossly underestimated the displacement forces required to be borne by an endoprosthesis to maintain its position? We physicians did not know, 3 to 5 years ago, how drastically we had erred in our assumptions regarding displacement forces enjoyed by an aortic device. We did not know the gravity of treating short or conical necks with devices designed for achieving fixation and seal within an infrarenal neck. Numerous physicians did not understand the importance of placing the fabric of a graft immediately below the renal arteries. Finally, many physicians did not understand the critical importance of proximal fixation. Are we any better off today?

To a certain extent, things have improved from the days of early devices. Failures akin to those observed with the Stentor (formerly MinTec, the Bahamas) and Vanguard (Boston Scientific Corporation, Natick, MA) devices,¹² such as component separation or fabric tears, have become rare, although failures still exist in the form of device migration and unanticipated progression of the aneurysmal disease. How many surgeons have operated on patients with aneurysms proximal to a previously repaired AAA? Why does this occur? Was the initial surgeon so incompetent that he or she sutured the proximal anastomosis to obviously aneurysmal aorta? Unlikely.

A more probable scenario is that the extent of the aneurysmal disease was not appreciated until later, when the patient re-presented with degeneration of the historical proximal infrarenal neck. Will this same effect occur after endovascular repairs? Absolutely, and the potential for late disasters is frightening. There are well-documented studies noting a considerable incidence of proximal neck dilation.¹³⁻¹⁵ Unlike the sutured anastomosis of an open surgical repair, an endograft, relying solely on infrarenal fixation, will be swimming upstream in a torrential current. What will hold it in place? These concerns must be paramount to aortic interventionists if they expect their patients to survive more than a few years after the procedure. It was commonplace for surgeons to criticize our radiology colleagues when a beautiful completion angiogram was presented. Our retort was that nice pictures did not equate to durable results. Now, many of us are guilty of the same crime.

The large number of patients subjected to cavalier placement of endovascular grafts into unsuitable anatomies, who were then touted as clinical successes and relegated to the purgatory of an undefined follow-up paradigm, is disappointing. I believe that many physicians don't have the means or endurance to perform meticulous migration or aneurysm growth analyses for each follow-up visit. It is in the latter situation that we may be worse than 7 years ago, when all

patients were enrolled into clinical trials requiring adherence to specific anatomic inclusion criteria and subject to scrutinized follow-up. Today, when devices are frequently used outside of the prescribed instructions for use, in anatomy that is more challenging, the outcomes will be even less durable than clinical trials and preclinical analyses have led us to expect. It pains me to hear physicians who believe that suprarenal fixation will be the answer for complex anatomy, but who argue that it is not necessary for more straightforward anatomy. Do they disbelieve the studies on device migration? Is there not clear evidence that the infrarenal proximal neck will ultimately fail in a substantial percentage of patients? Why would we want excellent fixation in the setting of challenging anatomy, and only marginal stability in another situation?

"It remains clear that the presence or absence of suprarenal fixation does not affect the risk of renal deterioration."

The suprarenal aorta is more disease-resistant than the infrarenal aorta. This is clearly shown by the paucity of aneurysmal or occlusive disease that affects this aortic region. Why is this? Most explanations center upon the more stable biochemical composition of the aorta in regions of branches. This has the effect of limiting dilation to aortic segments, which is readily apparent in a patient manifesting aortic disease. Infrarenal aneurysms are most common, followed by thoracic aneurysms, whereas thoracoabdominal aneurysms are least frequently encountered. So, given the multitude of migration reports, and clear evidence that the proximal neck may not be as stable as we once assumed, where should an endovascular graft designed to treat AAAs be anchored? The resounding answer is the suprarenal visceral aortic segment, if such a practice is safe.

THE SAFETY OF SUPRARENAL STENTING

Several reports published during the past 5+ years attest to the safety of crossing the renal arteries with a bare stent. Computational fluid dynamic models demonstrated minimal velocity disturbances and negligible effects on renal perfusion.¹⁶ Animal testing also failed to produce concerns with bare stents across the renal arteries. In fact, I am not aware of any preclinical testing that has shown what would be considered a detrimental effect of suprarenal stents on the kidneys or the aorta. The proof of this is in the fact that almost

every major company in the interventional AAA arena has a device with a suprarenal stent (Zenith [Cook Incorporated, Indianapolis, IN], Talent [Medtronic AVE, Inc., Santa Rosa, CA], Fortron [Cordis Corporation, a Johnson & Johnson Company, Miami, FL], Powerweb [Endologix, Inc., Irvine, CA], to name a few). Would these companies have introduced devices into clinical trials or for commercial use if there were serious concern regarding the safety of suprarenal stenting? Likely not.

There are many clinical series that also support the safety of suprarenal stenting. The largest series published involves a comparison of the Zenith graft with open infrarenal aneurysm repair (primarily with infrarenal clamping).¹⁷ Not only were the two methods of repair identical with respect to adverse renal events based on a careful analysis of calculated creatinine clearance but the renal infarction rate was remarkably low in both groups with only 3 of 199 patients in the endovascular group. A subset of patients in each group had renal dysfunction but it should be noted that each patient with evidence of worsening renal function within the first 12 months of follow-up had improved renal dysfunction by the 24-month follow-up visit (Figure 1). It is critical to understand, as demonstrated in figure 1, that every patient with initially declining renal function showed dramatic improvement between 12 and 24 months. This implies a lack of continued insult from the placement of suprarenal stenting, and one would hypothesize the initial dysfunction relates to the procedure, or serial CT scanning rather than any aspect of transrenal fixation. The likely culprits include atheroemboli, ischemia, contrast nephropathy, or the inadvertent placement of fabric across the renal ostia. The latter is the result of careless deployment techniques, which I doubt will be the subject of future prospective evaluations. In fact, there was only a 1% incidence of renal artery occlusion in the endovascular arm, compared with a 1.4% incidence of renal artery occlusion in the open surgical arm. Each renal artery occlusion in the endovascular arm was noted to have graft material (the actual fabric) covering the renal orifice.

We do not plan on studying this phenomenon further, but we have heard of numerous reports indicating that one should not cover the renal artery with prosthetic graft material unless he wants the renal artery to occlude. There have been a number of underpowered studies that have demonstrated equivalence of suprarenal and infrarenal fixation systems with respect to renal adverse events.¹⁸⁻²⁰ It is unlikely that any clinical trial will ever be designed to compare the two means of device stabilization. It remains clear that the presence or

absence of suprarenal fixation does not affect the risk of renal deterioration.

MORE SUBTLE SUPRARENAL ISSUES

The use of a suprarenal stent to provide added fixation is attractive but some more subtle advantages exist from a device design and deployment perspective. Uncovered proximal stents generally allow for more accurate fabric deployment in the region of the renal arteries. This can be accomplished without the need to drag a device across the renal ostia or estimate where the fabric will land. Durable and strong proximal fixation can allow the body of the device to have limited columnar support, creating a device that will accommodate aortic tortuosity as well as future morphologic changes. The composite device, consisting of secure proximal fixation within a stable region of the aorta, flexible body, and accurate deployment, is desirable for the treatment of aortic aneurysms.

THE ABSOLUTE NECESSITY OF SUPRARENAL STENTING

At the 2005 EndoVascular Course in Marseille, France, Jaap Buth, MD, presented an analysis of device migration from the Eurostar database. The absence of a suprarenal stent was a very significant risk factor ($P < .0001$) for device migration. A word of caution must accompany all of the aforementioned analyses. Although we are singling out suprarenal stenting as the subject of this debate, it is the performance of the entire prosthesis rather than simply the suprarenal component that must be considered. For example, when separate analyses of the infrarenal devices in Professor Buth's study were conducted, not all of them were associated with an increased risk for device migration. It was only the AneuRx (Medtronic) graft (which was noted to have an incidence of 8.6%) that bore the brunt of fixation failures, whereas the incidence of migration with the Excluder (W. L. Gore & Associates, Flagstaff, AZ) graft was less but still higher than the Zenith device.

Similarly, the devices that incorporate suprarenal stents fixate within the suprarenal aorta differently. Some use barbs and radial force, and some use radial force only. There are different alloys of stents, differing stent lengths, periods, and amplitudes. The uncovered proximal stents have varying flexibility, and each stent, much like the rest of the endoprosthesis, can fracture or fail. Thus, the device as a whole must be considered.

It is clear that methods of establishing device fixation are additive. Radial force in the infrarenal aorta may be good, but infrarenal radial force coupled with suprarenal tissue ingrowth and barbs is better. This is

analogous to the belt and suspenders philosophy; however, the belt has already been proven to have a very real and significant incidence of failure.

At the end of the day, when we consider which device to use in a given patient, we must rely on clinical reports, preclinical analyses, an understanding of the fundamentals of aneurysmal disease of the aorta, and basic common sense to conclude that suprarenal stenting is both necessary and safe, not in some patients, but in almost all patients with infrarenal aneurysms. ■

Roy K. Greenberg, MD, is Director of Endovascular Research, The Cleveland Clinic Foundation, Cleveland, Ohio. He has disclosed that he receives research funding from Cook, Sulzer-Vascutek, and W. L. Gore & Associates; he is a paid consultant for Cook and receives royalties for patents licensed to Cook. Dr. Greenberg may be reached at (216) 445-5306; greenbr@ccf.org.

1. Greenhalgh RM, Brown LC, Kwong GP, et al. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomized controlled trial. *Lancet*. 2005;365:2179-2186.
2. Blankensteijn J, de Jong S, Prinssen M, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med*. 2005;352:2398-2405.
3. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomized controlled trial. *Lancet*. 2005;365:2187-2192.
4. Collin J, Murie J. Endovascular treatment of abdominal aortic aneurysm: a failed experiment. *Br J Surg*. 2001;88:1281-1282.
5. Collin J, Murie JA. Endovascular treatment of abdominal aortic aneurysm: a failed experiment. *Br J Surg*. 2001;88:1281-1282.
6. Ivancev K, Malina M, Lindblad B, et al. Abdominal aortic aneurysms: experience with the Ivancev-Malmö endovascular system for aortomonoiliac stent-grafts. *J Endovasc Surg*. 1997;4:242-251.
7. Resch T, Ivancev K, Brunkwall J, et al. Distal migration of stent-grafts after endovascular repair of abdominal aortic aneurysms. *J Vasc Interv Radiol*. 1999;10:257-264.
8. Malina M, Brunkwall J, Ivancev K, et al. Renal arteries covered by aortic stents: clinical experience from endovascular grafting of aortic aneurysms. *Europ J Vasc Endovasc Surg*. 1997;14:109-113.
9. Connors MI, Sternberg WI, Carter G, et al. Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. *J Vasc Surg*. 2002;36:476-484.
10. Cao P, Verzini F, Zannetti S, et al. Device migration after endoluminal abdominal aortic aneurysm repair: analysis of 113 cases with a minimum follow-up of 2 years. *J Vasc Surg*. 2002;35:229-235.
11. Lee J, Lee J, Aziz I, et al. Stent-graft migration following endovascular repair of aneurysms with large proximal necks: anatomical risk factors and long-term sequelae. *J Endovasc Ther*. 2002;9:652-654.
12. Beebe HG. Lessons learned from aortic aneurysm stent graft failure: observations from several perspectives. *Semin Vasc Surg*. 2003;16:129-138.
13. Illig K, Green R, Ouriel K, et al. Fate of the proximal aortic cuff: implications for endovascular aneurysm repair. *J Vasc Surg*. 1997;26:492-499.
14. Sonesson B, Malina M, Ivancev K, et al. Dilatation of the infrarenal aneurysm neck after endovascular exclusion of abdominal aortic aneurysm. *J Endovasc Surg*. 1998;5:195-200.
15. Matsumura J, Chaikof E. Continued expansion of aortic necks after endovascular repair of abdominal aortic aneurysms. EVT Investigators. Endovascular Technologies Inc. *J Vasc Surg*. 1998;28:422-430.
16. Liffman K, Lawrence-Brown MM, Semmens JB, et al. Suprarenal fixation: effect on blood flow of an endoluminal stent wire across an arterial orifice. *J Endovasc Ther*. 2003;10:260-274.
17. Greenberg RK, Chuter TA, Lawrence-Brown M, et al. Analysis of renal function after aneurysm repair with a device using suprarenal fixation (Zenith AAA Endovascular Graft) in contrast to open surgical repair. *J Vasc Surg*. 2004;39:1219-1228.
18. Alsac JM, Zarins CK, Heikkinen MA, et al. The impact of aortic endografts on renal function. *J Vasc Surg*. 2005;41:926-930.
19. Alric P, Hinchliffe RJ, Picot MC, et al. Long-term renal function following endovascular aneurysm repair with infrarenal and suprarenal aortic stent-grafts. *J Endovasc Ther*. 2003;10:397-405.
20. Parmer SS, Carpenter JP. Endovascular aneurysm repair with suprarenal versus infrarenal fixation: a controlled study of renal effects. *Vascular Meeting Chicago, IL*. Jun 18; 2005.